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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,280	12/10/2001	Frank Himmelsbach	5/1262	7351

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EXAMINER

PATEL, SUDHAKER B

ART UNIT PAPER NUMBER

1624

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/1/04

Office Action Summary

Application No.

10/016,280

Applicant(s)

HIMMELSBACH ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 4/20/04
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicants' communication paper dated 1/8/04 is acknowledged.

Applicants have, cancelled claims 10-11, amended claims 1-9, and presented new claims 12, 13. Therefore, the claims in this application are the claims 1-9, 12, 13.

Applicants' above stated amendments to claims, cancellation of claims together with their arguments and remarks have been reviewed, but not found persuasive for the allowance of this case as is for the reasons stated below. See interview summary dated 4/20/04 enclosed with this communication.

Election/Restrictions

2. Applicants have elected species of generic Formula (I) of claim 1, namely, compound of Example 3 recited in page 44 lines 20-22 (= 4-[(3-Chloro-4-fluorophenyl) amino]-6-[[4-(N, N-diethyl amino)-oxo-2-buten-1-yl] amino]-7-cyclopropylmethoxyquinazoline), claims (in part) 1-11, drawn to compounds, compositions, method of use, and the first recited process of making the same for the generic Formula (I). The restriction/election has been made FINAL in earlier Office communication paper dated 7/8/03.

Rejections maintained:

3. Applicants' above stated arguments, remarks and amendments have been reconsidered but not found persuasive for withdrawal of rejections made under 35 U.S.C. 112 paragraph second for claims 1-5, 7, 8, 9, 12, 13 for reasons already stated in prior Office communication paper dated 7/8/03. Following additional reasons apply.

(A). Claim 1 recites C variable as: "1,3-allenylene, 1,1- or 1,2-vinylene". It is not very clear as to what applicants want to present with. Ally group consists of 3 carbon atoms with 1 double bond. Alternatively it is a propylene group with 1 double bond. Similarly, vinyl group consists of 2 carbon atoms with 1 double bond". Correction to what is exactly and definitely claimed group(s) is required.

(B). Claims 1, 3 recites C variable as: "1,3-butadien-1, 4-ylene". 1,3-butadien is having a core: "CH₂=CH-CH=CH₂ wherein the double bonds are carbon atoms 1 and 3 respectively". Are diacetylene(s) with 4 carbon atoms excluded or a mixture of a double bond and a triple bond in a 4-carbon chain/bridge? Correction to exact and definite structure is required.

(C). Claims 1, 3 recite C components as: "ethynylene group". Is acetylene group excluded? Correction to exact and definite structure is required.

(D). Claims 9, 13 recite: "or preventing". Cancellation is required.

(E). Claim 12 recites: "with one or more inert carriers and/or diluents". A pharmaceutical composition with a carrier is different from with a carrier and a diluent. With other combination(s) either alone or in plurals the nature and composition(s) are

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also different. Correction to: "with an inert carrier and with or without a diluent" is required.

(F). Claims 9, 13 recite "benign or malignant tumors". Correction to a single, specific and definite tumor that can be treated by the invention is required.

(G). Claims 1-9, are presented after amendments to delete prior art(s), but based on above stated reasons it is difficult to read what is exactly claimed. E.g. The reference Wissner et al (WO 9909016, also cited as Chemical Abstract DN 130:196664).

Claims 2,4,5,7,8 are rejected because they are dependent on the rejected claim(s).

Priority

4. This application claims benefit of 60146644 filed 7/30/1999. It also claims the priority to foreign applications (1). Germany 19928281.1 filed 6/21/1999. (2). Germany 10023085.7 5/11/200. On going thru' the records and the eDAN electronic file as received by the Examiner, this file is missing the certified true copies of both of the foreign files stated above. Applicants are urged to provide the same to complete the records of e-DAN system prior to allowance. See interview summary attached with this communication.

Specification

5. The specification is amended as per applicants page 2 of the amendment dated 1/1/8/04.

Conclusion

Allowable Subject Matter

6. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 1-5,7-9,12,13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and others together with other requirements, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. The closest prior Art(s) of record reference. '226(EP566226) is teaching making of quinazoline tyrosine kinase-inhibiting anticancer agents.

The ref. '226 chemical core is:

"4,6-Quinazolinediamine, 7-methoxy-N-4-(3methylphenyl)"

The ref. '226 differs from the instant claims by having CH₃-O- instead of -O-CH₂-Cycloalkyl, and -NH₂ instead of -NH-CO-CH=CH-CH₂-N(alkyl)₂.

The other ref. '983(WO 9738983) teaches making of irreversible inhibitors of tyrosine kinase. See compound of Example 55 on page 123, and the compounds of claim 1 on pages 152-154.

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The references either alone or in combination do not suggest totarrive at the instant claims as presented after amendments and cancellation of claims 10,11 .

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671.

The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James O. Wilson at (571) 272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sudhaker B. Patel, D.Sc. Tech.
April 20, 2004


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